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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,033	09/25/2000	Roderic M K Dale	09388.0015.01	5652

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EXAMINER
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KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/669,033

Applicant(s)

DALE, RODERIC M K

Examiner

Young J. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-28 is/are allowed.
- 6) ☒ Claim(s) 18-24 is/are rejected.
- 7) ☒ Claim(s) 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on November 24, 2003 has been entered.

### ***Preliminary Remark***

The Office acknowledges the revocation of old and grant of new power of attorney in the correspondence received on February 11, 2004.

Claims 18-28 are pending are under prosecution.

All rejections not reiterated hereto are withdrawn based on further reconsideration of Applicants' arguments received on November 24, 2003.

### ***Priority***

Applicants' preliminary amendment received on September 25, 2000, amending the specification to claim benefit under 35 U.S.C. 120 is acknowledged.

### ***Drawings***

New corrected drawings are required in this application because the "Acid Sensitive" structure in Figure 2 overlaps the printed application serial number due to improper margin of

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the figure. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### ***Claim Objections***

Claim 18 is objected to because of the following informalities: Claim 18 appears to contain a typographical error because sub-step (e) references "said arrays," but the method involves the use of an array (in singular). Further, Applicants have amended sub-step (b) of the claim to amend the phrase, "said arrays" to "said array". Therefore, it appears that the phrase, "said arrays" is a typographical error. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 and its dependent claims 19-24 are indefinite for the recitation of the phrase, "modified polynucleotide comprising a determinable nucleic acid," because it is unclear what is meant by a nucleic acid that is determinable. For the purpose of prosecution, the phrase is assumed to mean the modified polynucleotide comprising a determinable nucleic acid sequence.

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Claim 18 and its dependent claims 19-24 are further indefinite for the recitation of the phrase, "contacting the array of modified polynucleotides with a first collection of labeled nucleic acid comprising a sequence substantially complementary to *a nucleic acid of said array*," because the array is described as comprising modified polynucleotides, rendering the claim confusing as to whether the first collection of the labeled nucleic acids are complementary to the modified polynucleotides or another set of nucleic acids. The confusion is evidenced by sub-step (d) wherein, after the first collection of the labeled nucleic acids are washed off, a second collection of labeled nucleic acid are contacted with "modified polynucleotide of said array."

Claim 18 and its dependent claims 19-24 recite the limitation "the modified oligonucleotides" in the phrase, "wherein the modified oligonucleotides are characterized by a pH..." appearing after sub-step (e). There is insufficient antecedent basis for this limitation in the claim. Amending the claim to recite "the modified polynucleotides" would overcome this rejection.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 18-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 18 of U.S. Patent No. 6,562,569 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claim 18 of the U.S. Patent No. 6,562,569 (hereto referred to as '569 patent) is as follows:

A method for selectively identifying DNA in a biological sample which contains DNA, comprising:

a) contacting said sample with the array of claim 1, wherein the array of claim 1 is described as:

i) an array comprising a plurality of modified oligonucleotides stably associated with a surface of a support, wherein in each oligonucleotide is characterized by: an oligonucleotide backbone structure modified with at least one p-ethoxy internucleoside linkage (imparting nuclease resistance according to column 5, lines 51-65), having a binding affinity greater than that of a corresponding non-modified oligonucleotide, wherein the oligonucleotides are further characterized by a pH stability of at least one hour at 37°C at a pH range of about 0.5 to about 6.0;

b) allowing the DNA in the biological sample to hybridize to a modified sequence of the array;

c) analyzing the results of the hybridizing;

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- d) removing sequences hybridized to sequences of the array using a removing agent selected from the group consisting of a solution having a pH of less than 6.0 and a nuclease which enzymatically destroys natural nucleic acid sequences; and
- e) repeating (a), (b), (c) and (d) with a *second* biological sample.

Claim 18 of the instant application is drawn to a method of detecting a nucleic acid sequences in two or more collections of nucleic acid molecules, the method comprising the steps of using an array of modified polynucleotides (as described by claim 1-a of '569 patent); contacting the array of modified polynucleotides with a first collection of labeled nucleic acid (as described by claim 1-b of the '569 patent); detecting (or analyzing) the results of the hybridization (as described by claim 1-c of the '569 patent); removing the hybridized nucleic acid sequence from the array by incubation of the array with acid solution of pH 1-2 (as described by claim 1-d of the '569 patent); contacting the array with a second labeled nucleic acid followed by their detection (as described by claim 1-e of the '569 patent). The difference between claim 18 of the instant application and claim 18 of the '569 patent is that the instant method employs an acidic solution of pH 1-2 for the removal of the hybridized nucleic acid, while the method of the '569 patent employs a solution of pH of less than 6.0. However, such difference is determined as being obvious because claim 18 of the '569 patent describes the modified polynucleotides of the array as having the characteristic of pH stability of at least one hour at 37°C at a pH in a range of about 0.5 to 6.0. Therefore, given this characteristic, the use of a solution of pH 1-2, which is well within the range of the modified polynucleotide stability, would have been an obvious modification to an ordinarily skilled artisan at the time the invention

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was made. As to the differences between the use of DNA in the method of '569 patent versus the more generic term of nucleic acid sequences in the instant claim, the use of the term DNA would meet the more generic term nucleic acids used by the instant application.

While the limitation of instant claims 19 and 20 drawn to whether the first and second nucleic acids comprise different or the same labels, the labeling technique of the target nucleic acid in an array method is well established and within the purview of an ordinarily artisan. On column 20, lines 1-10 of the '569 patent, such well-established knowledge is also evidenced.

Claim 21 of the instant application recites that the method employs an incubation of the hybridized array with a nuclease for the purpose of removing the hybridized nucleic acid. Claim 18 of '569 patent recites this method of removal as an alternative method, rendering this claim also obvious.

Claim 22 of the instant application further recites that each of the different modified polynucleotides is attached to solid surface in a different predefined region. This recitation is also considered to be obvious in view of the conventional meaning of the term array of oligonucleotides. By definition, the array of oligonucleotides comprises oligonucleotides that are immobilized on a predefined region. Such knowledge is evidenced in column 16, lines 46-48 of '569 patent.

Claim 23 of the instant application recites that the polynucleotide sequences have different sequences and that the polynucleotide is at least 4 nucleotides in length. An array of which comprises oligonucleotides of different sequences as well as their appropriate lengths are obvious and well within the purview of an ordinarily skilled artisan as well as evidenced by claim 7, column 10, lines 12-13, and column 4, lines 41-45 of the '569 patent.

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Claim 24 of the instant application recites the last step as incubating the array with an acid solution of pH 1-2, whereby array is regenerated for reuse. The nature of the invention of '569 patent is the reuse of the array via incubating the array with an acid solution or a nuclease. Such is already disclosed by claim 18 of '569 patent. With regard to the obviousness of pH being 1-2, such as been already discussed above.

Therefore, for the above reasons, the invention as claimed is obvious over claim 18 of '569 patent.

Claims 18-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No. 6,087,112. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claim 15 of the U.S. Patent No. 6,087,112 (hereto referred to as '112 patent) is as follows:

A method for analyzing comprising the steps of:

- a) contacting a first sample of naturally occurring nucleic acid sequences with an array comprised of a solid support having bound to its surface a plurality of modified nucleic acid sequences, said bound sequences characterized by acid resistance and nuclease resistance;
- b) allowing sequences of the sample to hybridize to the modified sequence of the array;
- c) analyzing the results of the hybridizing;

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- d) removing sequences hybridized to sequences of the array using a removing agent selected from the group consisting of a solution having a pH of less than 6.0 and a nuclease which enzymatically destroys natural nucleic acid sequences; and
- e) repeating (a), (b), (c) and (d) with a *second* sample of naturally occurring sequences.

Claim 18 of the instant application is drawn to a method of detecting a nucleic acid sequences in two or more collections of nucleic acid molecules, the method comprising the steps of using an array of modified polynucleotides and contacting the array of modified polynucleotides with a first collection of labeled nucleic acid (as described by claim 1-a and 1-b of the '112 patent); detecting (or analyzing) the results of the hybridization (as described by claim 1-c of the '112 patent); removing the hybridized nucleic acid sequence from the array by incubation of the array with acid solution of pH 1-2 (as described by claim 1-d of the '112 patent); contacting the array with a second labeled nucleic acid followed by their detection (as described by claim 1-e of the '112 patent). The difference between claim 18 of the instant application and claim 18 of the '112 patent is that the instant method employs an acidic solution of pH 1-2 for the removal of the hybridized nucleic acid, while the method of the '112 patent employs a solution of pH of less than 6.0. However, such difference is determined as being obvious because '112 patent describes the modified nucleic acids of the array as having the characteristic of pH stability of at least one hour at 37°C at a pH in a range of about 0.5 to 6.0 (see claim 13), with particular emphasis at pH 1-2 (column 3, lines 21). Therefore, given this characteristic, the use of a solution of pH 1-2, which is well within the range of the modified nucleic acid stability, would have been an obvious modification to an ordinarily skilled artisan at the time the invention was made. As to the differences between the use of naturally occurring

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nucleic acid sequences in the method of '112 patent versus the more generic term of nucleic acid sequences in the instant claim, whether explicitly recited or not, the methods require that the target nucleic acids be naturally occurring since they must be removed from the arrays by the use of a nuclease.

While the limitation of instant claims 19 and 20 drawn to whether the first and second nucleic acids comprise different or the same labels, the labeling technique of the target nucleic acid in an array method is well established and within the purview of an ordinarily artisan. On column 20, lines 48-60 of the '112 patent, such well-established knowledge is also evidenced.

Claim 21 of the instant application recites that the method employs an incubation of the hybridized array with a nuclease for the purpose of removing the hybridized nucleic acid. Claim 15 of '112 patent recites this method of removal as an alternative method, rendering this claim also obvious.

Claim 22 of the instant application further recites that each of the different modified polynucleotides is attached to solid surface in a different predefined region. This recitation is also considered to be obvious in view of the conventional meaning of the term array of oligonucleotides. By definition, the array of oligonucleotides comprises oligonucleotides that are immobilized on a predefined region. Such knowledge is evidenced in column 1, lines 53-55 of '112 patent.

Claim 23 of the instant application recites that the polynucleotide sequences have different sequences and that the polynucleotide is at least 4 nucleotides in length. An array of which comprises oligonucleotides of different sequences as well as their appropriate lengths are

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obvious and well within the purview of an ordinarily skilled artisan as well as evidenced by claim 14, column 10, lines 10-15, and column 4, lines 35-40 of the '112 patent.

Claim 24 of the instant application recites the last step as incubating the array with an acid solution of pH 1-2, whereby array is regenerated for reuse. The nature of the invention of '112 patent is the reuse of the array via incubating the array with an acid solution or a nuclease. Such is already disclosed by claim 15 of '112 patent. With regard to the obviousness of pH being 1-2, such as been already discussed above.

Therefore, for the above reasons, the invention as claimed is obvious over claim 15 of '112 patent.

#### ***Conclusion***

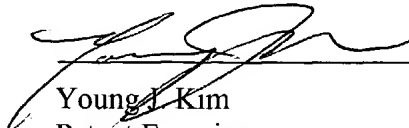
Claims 18-24 are rejected. Claims 25-28 are free of prior art.

#### ***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial

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documents, faxes can be sent directly to the Examiner at (517) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0507.

A handwritten signature in black ink, appearing to read 'Young J. Kim', is written over a horizontal line.

Young J. Kim  
Patent Examiner  
Art Unit 1637  
3/8/04